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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/991,964	11/26/2001	Franz-Josef Rubroder	02481.1671-01	1450

22852 7590 12/20/2002

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WASHINGTON, DC 20006

EXAMINER

CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 12/20/2002

/1

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/991,964

Applicant(s)

RUBRODER ET AL.

Examiner

Olga N. Chernyshev

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-77 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 23-77 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Claims s 47 and 77 have been amended as requested in the amendment of Paper No. 9, filed on October 08, 2002. Claims 23-77 are pending and under examination in the instant application.
2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
4. Applicant's arguments filed on October 08, 2002 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 103

5. Claims 23-34, 40-46, 48-64 and 70-77 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Flaa et al. (1996, WO 96/27661) and Mikura et al. (1985, EP 158487) and further in view of Ahmad et al. (1983, JAOCS, 60, 4, pp.837-840) and Santha et al. (1979, Indian J.Anim.Sci., 49, 1, pp.37-41) for reasons of record in section 5 of Paper No. 8.

Applicant traverses the rejection on the premises that Flaa does not teach using cysteine for a process for a process for the storage of a protein but used cysteine derivative NAC (N-acetyl-cysteine); Mikura et al. also did not use cysteine for storage of protein but used cysteine derivatives; and Ahmad et al. and Santha et al. used cysteine for storage of oils, which are lipids

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and not proteins (pages 3-5 of the Response). This has not been found to be persuasive for the following reasons.

The fact that proteins are subject to oxidation relates to old and well-established scientific and general knowledge. The fact that cysteine is the best-known biologically available non-toxic, temperature-resistant reducing agent is confirmed by its routine use for protection of proteins and oils from oxidation. Applicant's argument that references of Flaa and Mikura et al. do not specifically used cysteine but cysteine derivatives is not persuasive because if the references did teach cysteine, the rejection would be made under 35 U.S.C. 102 and not 35 U.S.C. 103(a). Further, because claim 23 does not include any time limitations, one of ordinary skill in the art would reasonably believe that addition of any amount of cysteine would delay the temporal decrease in the effective concentration of a protein based on the fact that cysteine as a reducing agent would prevent oxidation of the protein. Moreover, a skilled artisan would readily appreciate the fact that the addition of high amounts of cysteine would logically lead to better protection against oxidative damage.

New grounds of rejection

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 23, 24, 33, 40-42, 48-54, 63 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Hong Qi et al. (1995, PDA J. Pharmaceutical Science and Technology, 49, 6, 289-292, reference of Paper No. 5, parent application 09/608,297).

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Claims 23, 24, 33, 40-42, 48-54, 63 are directed to a process for the storage of a protein in an aqueous solution comprising adding an amount of cysteine effective to delay the decrease of the effective concentration of the protein. Hong Qi et al. describe that addition of cysteine prolongs the stability of a protein, insulinotropin up to 100 days (see Figure 9 and text on page 292), thus meeting the limitations of claims 23, 24, 33, 40-42, 48-54, 63.

Claim Rejections - 35 USC § 103

7. Claims 25-32, 43-47, 55-62, 73-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hong Qi et al. as applied to claims 23, 24, 33, 40-42, 48-54, 63 above.

Claims 25-32, 43-47, 55-62, 73-77 are directed to a process for the storage of a protein in an aqueous solution comprising adding an amount of cysteine effective to delay the decrease of the effective concentration of the protein, wherein the protein is prepared in different microorganisms. The scope of the claims 25-32, 43-47, 55-62, 73-77 is different from the claims 23, 24, 33, 40-42, 48-54, 63, which are fully anticipated by publication of Hong Qi et al., see section 6 above, only in the way the protein is produced. The product-by-process limitations recited in these claims do not materially limit the product produced thereby. Therefore, it would have been obvious for one of ordinary skill in the art to use any available and widely used modern techniques for expression and purification of any protein, including animal insulin.

Conclusion

8. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003.

The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-0294 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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Olga N. Chernyshev, Ph.D.
December 20, 2002

OC

JOHN ULM
PRIMARY EXAMINER
GROUP 1800

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